k123929

BEGO

5 510(k) Summary

MAR 1 4 2013

Owner's name:	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Address:	Wilhelm-Herbst-Str. 1 28359 Bremen / Germany
Phone:	+49 421 2028 112
Fax:	+49 421 2028 44-112
Contact person:	Dr. Heike Gustke
Date prepared:	November 20, 2012
Device name:	BegoPal+
Common name:	dental alloy
Classification name:	base metal alloy (21 CFR 872.3710, product code EJH)
Predicate devices:	Wirobond C K032136 Wirobond C+ 510(k) exempt Callisto CP+ 510(k) exempt

Device Description

BegoPal+ is a palladium containing cobalt-chromium alloy for fabrication of porcelain fused to metal dental restorations. BegoPal+ is available as powder and is processed by selective laser melting.

Indications for use

BegoPal+ is a porcelain-fused-to-metal (PFM) noble alloy. It is suitable for fabrication of crown and bridge restorations. BegoPal+ is available as powder and is processed by selective laser melting.

SLM rapid prototyping devices that are compatible with BegoPal+

EOSINT M 270, EOSINT M 280
(Manufacturer: EOS GmbH, Robert-Stirling-Ring 1, 82152 Krailling, Germany)
SLM 125^{HL}, SLM 250^{HL}
(Manufacturer: SLM Solutions GmbH, Roggenhorster Straße 9c, 23556 Lübeck, Germany)

Comparison to predicate devices

BegoPal+ is substantially equivalent to the predicate devices regarding to the indications for use, technical parameters and biocompatibility. The differences between BegoPal+ and predicate devices are product shape, processing and material composition.
The test results according to ISO 22674, ISO 9693-1, ISO 10271 and ISO 10993 show that the safety and effectiveness have not been affected by the introduction of palladium in a cobalt-chromium alloy and by the different processing of the alloy. Based on the test results BegoPal+ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2013

Dr. Heike Gustke
BEGO Bremer Goldschlägerei Wilhelm-Herbst GmbH & Company, KG
Wilhelm-Herbst-Strasse 1
Bremen, Germany 28359

Re: K123929
Trade/Device Name: BegoPal+
Regulation Number: 21 CFR 872.3710
Regulation Name: Base Metal Alloy
Regulatory Class: II
Product Code: EJH
Dated: December 18, 2012
Received: December 20, 2012

Dear Dr. Gustke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123929

Device Name: BegoPal+

Indications For Use:

BegoPal+ is a porcelain-fused-to-metal (PFM) noble alloy. It is suitable for fabrication of crown and bridge restorations. BegoPal+ is available as powder and is processed by selective laser melting.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.03.11
13:05:59 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123929